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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/654,228	09/03/2003	Michael G. Hayek	P127C	4744

27752 7590 06/20/2006

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EXAMINER	
STITZEL, DAVID PAUL	

ART UNIT	PAPER NUMBER
1616	

DATE MAILED: 06/20/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/654,228	HAYEK ET AL.	
	Examiner	Art Unit	
	David P. Stitzel, Esq.	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-6 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-6 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 9/3/03; 9/3/03.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

OFFICIAL ACTION

Status of Claims

Claims 1-6 are currently pending and therefore examined herein on the merits for patentability.

Statutory Double Patenting

A statutory double patenting rejection of the "same invention" type finds its support in the language of 35 U.S.C. § 101, which states in part that "whoever invents or discovers any new and useful process ... or composition of matter ... may obtain ***a*** patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 164 USPQ 619 (CCPA 1970). A statutory type (35 U.S.C. § 101) double patenting rejection can be overcome by either canceling or amending the conflicting claims so that they are no longer coextensive in scope. However, the filing of a terminal disclaimer ***cannot*** overcome a double patenting rejection based upon 35 U.S.C. § 101.

Claims 4-6 of the instant application are rejected under 35 U.S.C. § 101 as claiming the same invention as that of conflicting claims 1-3 of U.S. Patent 6,641,836 (hereinafter the conflicting Hayek '836 patent).

Claim Rejections - 35 U.S.C. § 102

The following are quotations of the appropriate paragraphs of 35 U.S.C. § 102, which form the basis of the anticipation rejections as set forth under this particular section of the Official Action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

1. Claims 1 and 2 are rejected under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent 6,133,317 (hereinafter the Hart '317 patent).

Claims 1 and 2 of the instant application are directed to a method for enhancing immune response in a dog comprising feeding said dog a dog food composition, wherein said dog food composition comprises garlic, which is present in an amount from about 0.1 wt. % to about 1.0 wt. % (i.e., from about 1 g/kg to about 10 g/kg).

With respect to claims 1 and 2 of the instant application, the Hart '317 patent discloses a method for improving the immune system of a dog comprising feeding said dog a dry dog food composition, wherein said dry dog food composition comprises oxalic acid and/or oxalate in the form of garlic, which is present in a therapeutically effective amount of about 2.2 g/kg (abstract; column 8, lines 24-37; column 10, lines 59-62; column 14, lines 6-10 and 40-46; column 16, lines 1-50; column 18, lines 22-43; column 24, lines 18-29; column 25, lines 17-20; column 27, lines 10-18; column 28, lines 26-28 and 45-49; column 29, lines 7-8 and 40-59; column 33, lines 4-18; column 38, examples 50-51; column 39, examples 56 and 61; column 41, examples 74-75; column 42, examples 80 and 82; column 43, examples 89 and 90; column 45, examples 109-110; and column 46, example 115).

2. Claims 1-3 are rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent 5,141,755 (hereinafter the Weisman '755 patent).

Claims 1-3 of the instant application are directed to a method for enhancing immune response in a dog comprising feeding said dog a dry dog food composition, wherein said dry dog food composition comprises: garlic, which is present in an amount from about 0.1 wt. % to about 1.0 wt. % (i.e., from about 1 g/kg to about 10 g/kg); protein, which is present in an amount from about 20 wt. % to about 40 wt. %; fat, which is present in an amount from about 4 wt. % to about 30 wt. %; and fiber, which is present in an amount from about 1 wt. % to about 11 wt. %.

With respect to claims 1-3 of the instant application, the Weisman '755 patent discloses a dry dog food composition, wherein said dry dog food composition comprises: garlic, which is present in an amount from about 0.001 wt. % to about 15 wt. % (i.e., from about 0.009 g/kg to about 150 g/kg); protein, which is present in an amount from about 10 wt. % to about 30 wt. %; fat, which is present in an amount from about 4 wt. % to about 35 wt. %; and fiber, which is present in an amount from about 2 wt. % to about 3 wt. % (column 1, lines 6-8; column 2, lines 36-39 and 55-68; column 3, lines 1-9, 41-43 and 66-67; column 4, lines 59-62; column 5, lines 1-10 and 55-61; column 6, lines 21-25 and 54-59; column 7, lines 19-25; and claims 11 and 12).

The "discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer." See *Atlas Powder Co. v. Ireco Inc.*, 51 USPQ 2d 1943, 1947 (Fed. Cir. 1999). Therefore, merely claiming a new use, new function or unknown property, which is inherently present in the prior art, does not necessarily make the claim patentable. See *In re Best*, 195 USPQ 430, 433 (CCPA 1977); and MPEP § 2112. Furthermore "products of identical chemical composition can not

have mutually exclusive properties," since a chemical composition and its properties are inseparable. See *In re Spada*, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990); and MPEP § 2112. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. See MPEP § 2112.

3. Claim 1 is rejected under 35 U.S.C. § 102(a) and (e) as being anticipated by U.S. Patent 5,965,153 (hereinafter the Allen '153 patent).

Claim 1 of the instant application is directed to a method for enhancing immune response in a dog comprising feeding said dog a dog food composition, wherein said dog food composition comprises an effective amount of garlic.

With respect to claim 1 of the instant application, the Allen '153 patent discloses a method for reducing fungal infections and promoting the health of a dog comprising feeding said dog a dietary supplement composition, wherein said dietary supplement composition comprises an effective amount of garlic (abstract; column 1, lines 7-9, 31-44 and 56-63; column 2, lines 4-14, 23-30, 41-50 and 60-65; and claims 1, 2, 4, 6, 7, 9 and 10).

The "discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer." See *Atlas Powder Co. v. Ireco Inc.*, 51 USPQ 2d 1943, 1947 (Fed. Cir. 1999). Therefore, merely claiming a new use, new function or unknown property, which is inherently present in the prior art, does not necessarily make the claim patentable. See *In re Best*, 195 USPQ 430, 433 (CCPA 1977); and MPEP § 2112. Furthermore "products of identical chemical composition can not have mutually exclusive properties," since a chemical composition and its properties are inseparable.

See *In re Spada*, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990); and MPEP § 2112. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. See MPEP § 2112.

4. Claim 1 is rejected under 35 U.S.C. § 102(a) and (e) as being anticipated by U.S. Patent 5,976,549 (hereinafter the Lewandowski '549 patent).

Claim 1 of the instant application is directed to a method for enhancing immune response in a dog comprising feeding said dog a dog food composition, wherein said dog food composition comprises an effective amount of garlic.

With respect to claim 1 of the instant application, the Lewandowski '549 patent discloses a method for reducing fungal infections and promoting the health of a dog comprising feeding said dog a dietary supplement composition, wherein said dietary supplement composition comprises an effective amount of garlic (abstract; column 1, lines 9-15; column 2, lines 40-51; column 3, lines 64-65; column 4, lines 1-67; column 5, lines 1-11; and claims 1-5).

The "discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer." See *Atlas Powder Co. v. Ireco Inc.*, 51 USPQ 2d 1943, 1947 (Fed. Cir. 1999). Therefore, merely claiming a new use, new function or unknown property, which is inherently present in the prior art, does not necessarily make the claim patentable. See *In re Best*, 195 USPQ 430, 433 (CCPA 1977); and MPEP § 2112. Furthermore "products of identical chemical composition can not have mutually exclusive properties," since a chemical composition and its properties are inseparable. See *In re Spada*, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990); and MPEP § 2112. Therefore, if the prior

art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. See MPEP § 2112.

Claim Rejections - 35 U.S.C. § 103

The following is a quotation of the appropriate paragraph of 35 U.S.C. § 103, which forms the basis of the obviousness rejections as set forth under this particular section of the Official Action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. § 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

1. Claims 1-3 are rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent 5,141,755 (hereinafter the Weisman '755 patent).

Claims 1-3 of the instant application are directed to a method for enhancing immune response in a dog comprising feeding said dog a dry dog food composition, wherein said dry dog food composition comprises: garlic, which is present in an amount from about 0.1 wt. % to about 1.0 wt. % (i.e., from about 1 g/kg to about 10 g/kg); protein, which is present in an amount from about 20 wt. %

to about 40 wt. %; fat, which is present in an amount from about 4 wt. % to about 30 wt. %; and fiber, which is present in an amount from about 1 wt. % to about 11 wt. %.

With respect to claims 1-3 of the instant application, the Weisman '755 patent teaches a dry dog food composition, wherein said dry dog food composition comprises: garlic, which is present in an amount from about 0.001 wt. % to about 15 wt. % (i.e., from about 0.009 g/kg to about 150 g/kg); protein, which is present in an amount from about 10 wt. % to about 30 wt. %; fat, which is present in an amount from about 4 wt. % to about 35 wt. %; and fiber, which is present in an amount from about 2 wt. % to about 3 wt. % (column 1, lines 6-8; column 2, lines 36-39 and 55-68; column 3, lines 1-9, 41-43 and 66-67; column 4, lines 59-62; column 5, lines 1-10 and 55-61; column 6, lines 21-25 and 54-59; column 7, lines 19-25; and claims 11 and 12).

The Weisman '755 patent does not explicitly teach a method of administering said dry dog food composition to a dog for the specific purpose of enhancing immune response within said dog, as claimed in claims 1-3 of the instant application.

It would have been prima facie obvious to one of ordinary skill in the art at the time the instant application was filed to administer the dry dog food composition of the Weisman '755 patent, to a dog, as reasonably suggested by the Weisman '755 patent. One of ordinary skill in the art at the time the instant application was filed would have been motivated to administer to a dog the dry dog food composition of the Weisman '755 patent, so as to provide said dog with a nutritionally balanced diet, as reasonably suggested by the Weisman '755 patent. Upon administering to a dog the dry dog food composition of the Weisman '755 patent, one would intrinsically enhance the immune response of said dog, as claimed in the instant application. More specifically, since the Weisman '755 patent teaches a dry dog food composition that is an obvious variation over, if not identical or substantially identical to,

that of the instantly claimed composition, the prior art composition would intrinsically enhance the immune response of said dog, as instantly claimed.

Where Applicant claims a composition in terms of a function, property or characteristic and the composition of the prior art is the same as that of the claim but the function is not explicitly disclosed by the reference, the Examiner may make a rejection under both 35 U.S.C. 102 and 103. See MPEP § 2112. This same rationale should also apply to product and process claims claimed in terms of function, property or characteristic. *Id.* Where the claimed and prior art products are identical or substantially identical in structure or composition a prima facie case of either anticipation or obviousness has been established. See *In re Best*, 195 USPQ 430, 433 (CCPA 1977). Therefore, the prima facie case can be rebutted by evidence showing that the prior art products do not necessarily possess the characteristics of the claimed product. *Id.* "The PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his claimed product. Whether the rejection is based on 'inherency' under 35 U.S.C. 102, on 'prima facie obviousness' under 35 U.S.C. 103, jointly or alternatively, the burden of proof is the same." See *In re Fitzgerald*, 205 USPQ 594, 596 (CCPA 1980) (quoting *In re Best*, 195 USPQ 430, 433-34 (CCPA 1977)).

2. Claim 1 is rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent 5,965,153 (hereinafter the Allen '153 patent).

Claim 1 of the instant application is directed to a method for enhancing immune response in a dog comprising feeding said dog a dog food composition, wherein said dog food composition comprises an effective amount of garlic.

With respect to claim 1 of the instant application, the Allen '153 patent teaches a method for reducing fungal infections and promoting the health of a dog comprising feeding said dog a dietary supplement composition, wherein said dietary supplement composition comprises an effective amount of garlic (abstract; column 1, lines 7-9, 31-44 and 56-63; column 2, lines 4-14, 23-30, 41-50 and 60-65; and claims 1, 2, 4, 6, 7, 9 and 10).

The Allen '153 patent does not explicitly teach a method of feeding said dietary supplement composition to a dog for the specific purpose of enhancing immune response within said dog, as claimed in claim 1 of the instant application.

It would have been prima facie obvious to one of ordinary skill in the art at the time the instant application was filed to administer the dietary supplement composition of the Allen '153 patent, to a dog, as taught by the Allen '153 patent. One of ordinary skill in the art at the time the instant application was filed would have been motivated to administer to a dog the dietary supplement composition of the Allen '153 patent, so as to reduce fungal infections and promote the health of said dog, as reasonably suggested by the Allen '153 patent. Upon administering to a dog the dietary supplement composition of the Allen '153 patent, one would intrinsically enhance the immune response of said dog, as claimed in the instant application. More specifically, since the Allen '153 patent teaches feeding a dog a dietary supplement composition that is an obvious variation over, if not identical or substantially identical to, that of the instantly claimed composition, the prior art composition would intrinsically enhance the immune response of said dog, as instantly claimed.

Where Applicant claims a composition in terms of a function, property or characteristic and the composition of the prior art is the same as that of the claim but the function is not explicitly disclosed by the reference, the Examiner may make a rejection under both 35 U.S.C. 102 and 103. See MPEP §

2112. This same rationale should also apply to product and process claims claimed in terms of function, property or characteristic. *Id.* Where the claimed and prior art products are identical or substantially identical in structure or composition a prima facie case of either anticipation or obviousness has been established. See *In re Best*, 195 USPQ 430, 433 (CCPA 1977). Therefore, the prima facie case can be rebutted by evidence showing that the prior art products do not necessarily possess the characteristics of the claimed product. *Id.* "The PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his claimed product. Whether the rejection is based on 'inherency' under 35 U.S.C. 102, on 'prima facie obviousness' under 35 U.S.C. 103, jointly or alternatively, the burden of proof is the same." See *In re Fitzgerald*, 205 USPQ 594, 596 (CCPA 1980) (quoting *In re Best*, 195 USPQ 430, 433-34 (CCPA 1977)).

3. Claims 1 and 2 are rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent 5,976,549 (hereinafter the Lewandowski '549 patent).

Claims 1 and 2 of the instant application is directed to a method for enhancing immune response in a dog comprising feeding said dog a dog food composition, wherein said dog food composition comprises garlic, which is present in an amount from about 0.1 wt. % to about 1.0 wt. % (i.e., from about 1 g/kg to about 10 g/kg).

With respect to claims 1 and 2 of the instant application, the Lewandowski '549 patent teaches a method for imparting therapeutic benefits to a dog comprising feeding said dog a garlic coated and/or impregnated composition, wherein said garlic coated and/or impregnated composition comprises an

effective amount of garlic (abstract; column 1, lines 9-15; column 2, lines 40-51; column 3, lines 64-65; column 4, lines 1-67; column 5, lines 1-11; and claims 1-5).

The Lewandowski '549 patent does not explicitly teach a method of feeding said garlic coated and/or impregnated composition to a dog for the specific purpose of enhancing immune response within said dog, wherein said garlic coated and/or impregnated composition comprises garlic in an amount from about 0.1 wt. % to about 1.0 wt. % (i.e., from about 1 g/kg to about 10 g/kg), as claimed in claims 1-3 of the instant application.

With respect to claims 1 and 2 of the instant application, although the Lewandowski '549 patent teaches a method of feeding a garlic coated and/or impregnated composition to a dog, the Lewandowski '549 patent does not explicitly teach the instantly claimed range of garlic being present in an amount from about 0.1 wt. % to about 1.0 wt. % (i.e., from about 1 g/kg to about 10 g/kg). However, while the Lewandowski '549 patent does not explicitly teach the instantly claimed weight percent range of garlic, it is well within the purview of the skilled artesian to determine the optimal weight percent range of garlic by systematically adjusting the concentrations thereof during the course of routine experimentation. One of ordinary skill in the art at the time the instant application was filed would have been motivated to systematically adjust the concentrations of garlic during the course of routine experimentation so as to obtain a desired degree of therapeutic benefits, as reasonably suggested by the Lewandowski '549 patent (column 2, lines 40-51; column 4, lines 44-54). "Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." See *In re Aller*, 105 USPQ 233, 235 (CCPA 1955). "The normal desire of scientists or artisans to improve upon what is already generally

known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages." See *Peterson*, 65 USPQ2d 1379, 1382 (Fed. Cir. 2003).

It would have been prima facie obvious to one of ordinary skill in the art at the time the instant application was filed to administer the garlic coated and/or impregnated composition of the Lewandowski '549 patent, to a dog, as taught by the Lewandowski '549 patent. One of ordinary skill in the art at the time the instant application was filed would have been motivated to administer to a dog the garlic coated and/or impregnated composition of the Lewandowski '549 patent, so as to lower blood pressure, reduce blood cholesterol, promote cardiovascular activity, sooth the respiratory system, relieve gas and indigestion, reduce yeast infections, and provide a systemic insect (e.g., flea) repellant, as reasonably suggested by the Lewandowski '549 patent. Upon administering to a dog the garlic coated and/or impregnated composition of the Lewandowski '549 patent, one would intrinsically enhance the immune response of said dog, as claimed in the instant application. More specifically, since the Lewandowski '549 patent teaches feeding a dog a garlic coated and/or impregnated composition that is an obvious variation over, if not identical or substantially identical to, that of the instantly claimed composition, the prior art composition would intrinsically enhance the immune response of said dog, as instantly claimed.

Where Applicant claims a composition in terms of a function, property or characteristic and the composition of the prior art is the same as that of the claim but the function is not explicitly disclosed by the reference, the Examiner may make a rejection under both 35 U.S.C. 102 and 103. See MPEP § 2112. This same rationale should also apply to product and process claims claimed in terms of function, property or characteristic. *Id.* Where the claimed and prior art products are identical or substantially identical in structure or composition a prima facie case of either anticipation or

obviousness has been established. See *In re Best*, 195 USPQ 430, 433 (CCPA 1977). Therefore, the prima facie case can be rebutted by evidence showing that the prior art products do not necessarily possess the characteristics of the claimed product. *Id.* "The PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his claimed product. Whether the rejection is based on 'inherency' under 35 U.S.C. 102, on 'prima facie obviousness' under 35 U.S.C. 103, jointly or alternatively, the burden of proof is the same." See *In re Fitzgerald*, 205 USPQ 594, 596 (CCPA 1980) (quoting *In re Best*, 195 USPQ 430, 433-34 (CCPA 1977)).

4. Claims 1-3 are rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent 6,156,355 (hereinafter the Shields '355 patent).

Claims 1-3 of the instant application are directed to a method for enhancing immune response in a dog comprising feeding said dog a dry dog food composition, wherein said dry dog food composition comprises: garlic, which is present in an amount from about 0.1 wt. % to about 1.0 wt. % (i.e., from about 1 g/kg to about 10 g/kg garlic per dry composition); protein, which is present in an amount from about 20 wt. % to about 40 wt. %; fat, which is present in an amount from about 4 wt. % to about 30 wt. %; and fiber, which is present in an amount from about 1 wt. % to about 11 wt. %.

With respect to claims 1-3 of the instant application, the Shields '355 patent teaches a substantially dry dog food formulation for inhibiting the growth of pathogenic organisms and providing wellness support, wherein said substantially dry dog food formulation comprises: garlic; protein, which is present in an amount of greater than or equal to about 20 wt. %; fat, which is present in an amount of greater than or equal to about 10 wt. %; and fiber, which is present in an amount from

about 0.5 wt. % to about 10 wt. % and preferably from about a 2 wt. % to about a 4 wt. % maximum; wherein said substantially dry dog food formulation has a maximum moisture content of less than or equal to 10 wt. % (column 1, lines 18-20; column 4, lines 18-23 and 43-62; column 5, lines 58-60; column 6, lines 50-52; column 7, lines 16-20; column 8, lines 30-32 and 62-63; column 14, lines 52-54; column 15, line 57; column 16, lines 5-8; column 17, lines 22 and 31-34; column 18, lines 55 and 63-66; column 20, lines 29 and 36-39; column 21, line 64; column 22, lines 7-10; and claims 1-5).

The Shields '355 patent does not explicitly teach a method of administering said substantially dry dog food formulation to a dog for the specific purpose of enhancing immune response within said dog, wherein said substantially dry dog food formulation comprises garlic, which is present in an amount from about 0.1 wt. % to about 1.0 wt. % (i.e., from about 1 g/kg to about 10 g/kg), as claimed in claims 1-3 of the instant application.

With respect to claims 1-3 of the instant application, although the Shields '355 patent teaches utilizing garlic within said substantially dry dog food formulation, the Shields '355 patent does not explicitly teach the instantly claimed range of garlic being present in an amount from about 0.1 wt. % to about 1.0 wt. % garlic (i.e., from about 1 g/kg to about 10 g/kg garlic per dry composition). However, while the Shields '355 patent does not explicitly teach the instantly claimed weight percent range of garlic, it is well within the purview of the skilled artesian to determine the optimal weight percent range of garlic by systematically adjusting the concentrations thereof during the course of routine experimentation. One of ordinary skill in the art at the time the instant application was filed would have been motivated to systematically adjust the concentrations of garlic during the course of routine experimentation so as to obtain a desired degree of growth inhibition of pathogenic organisms and wellness support, as reasonably suggested by the Shields '355 patent. "Where the general

conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." See *In re Aller*, 105 USPQ 233, 235 (CCPA 1955). "The normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages." See *Peterson*, 65 USPQ2d 1379, 1382 (Fed. Cir. 2003).

It would have been prima facie obvious to one of ordinary skill in the art at the time the instant application was filed to administer the substantially dry dog food formulation of the Shields '355 patent, to a dog, as reasonably suggested by the Shields '355 patent. One of ordinary skill in the art at the time the instant application was filed would have been motivated to administer to a dog the substantially dry dog food formulation of the Shields '355 patent, so as to provide said dog with a nutritionally balanced diet that not only inhibits the growth of pathogenic organisms, but also provides wellness support, as reasonably suggested by the Shields '355 patent. Upon administering to a dog the substantially dry dog food formulation of the Shields '355 patent, one would intrinsically enhance the immune response of said dog, as claimed in the instant application. More specifically, since the Shields '355 patent teaches a substantially dry dog food formulation that is an obvious variation over, if not identical or substantially identical to, that of the instantly claimed invention, the prior art composition would intrinsically enhance the immune response of said dog, as instantly claimed.

Where Applicant claims a composition in terms of a function, property or characteristic and the composition of the prior art is the same as that of the claim but the function is not explicitly disclosed by the reference, the Examiner may make a rejection under both 35 U.S.C. 102 and 103. See MPEP § 2112. This same rationale should also apply to product and process claims claimed in terms of function, property or characteristic. *Id.* Where the claimed and prior art products are identical or

substantially identical in structure or composition a prima facie case of either anticipation or obviousness has been established. See *In re Best*, 195 USPQ 430, 433 (CCPA 1977). Therefore, the prima facie case can be rebutted by evidence showing that the prior art products do not necessarily possess the characteristics of the claimed product. *Id.* "The PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his claimed product. Whether the rejection is based on 'inherency' under 35 U.S.C. 102, on 'prima facie obviousness' under 35 U.S.C. 103, jointly or alternatively, the burden of proof is the same." See *In re Fitzgerald*, 205 USPQ 594, 596 (CCPA 1980) (quoting *In re Best*, 195 USPQ 430, 433-34 (CCPA 1977)).

Conclusion

Claims 1-3 are rejected because the claimed invention would have been anticipated and/or prima facie obvious to one of ordinary skill in the art at the time the invention was made since each and every element of the claimed invention, as a whole, is disclosed in and/or would have been reasonably suggested by the teachings of the cited prior art references. Claims 4-6 are rejected on the grounds of statutory double patenting.

Remarks

The following is a list of patents and publications, both foreign and domestic, and scientific journal articles made of record and considered pertinent to the Applicant's disclosure, but are not however currently relied upon in construing the claim rejections as set forth herein:

- U.S. Patent 6,133,318 (the Hart '318 patent);
- U.S. Patent 6,309,676 (the Lewandowski '676 patent);
- U.S. Patent 6,407,141 (the Hart '141 patent);

- U.S. Patent 6,465,020 (the Cheon '020 patent) (column 3, lines 26-28; and claim 1; specific gravity of garlic extract is from about 0.906 to about 0.913);
- U.S. Patent 6,488,950 (the Arand '950 patent) (column 3, lines 18-19; Figure 3; specific gravity versus weight percent of garlic extract);
- U.S. Patent 6,511,674 (the Arand '674 patent) (column 3, lines 18-19; Figure 3; specific gravity versus weight percent of garlic extract);
- U.S. Pre-Grant Patent Application Publication 2002/0015745 (the Hayek '745 publication);
- U.S. Pre-Grant Patent Application Publication 2002/0044978 (the Cheon '978 publication) ([0018] specific gravity of garlic extract is from about 0.906 to about 0.913);
- U.S. Pre-Grant Patent Application Publication 2003/0203019 (Cornelius '019 publication);
- International Patent Application Publication WO 99/48381 (the Allen '381 publication); and
- International Patent Application Publication WO 01/82719 (the Hayek '719 publication).

Contact Information

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to David P. Stitzel, M.S., Esq., whose telephone number is 571-272-8508. The Examiner can normally be reached on Monday-Friday, from 7:30AM-6:00PM.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Mr. Johann Richter, Ph.D., Esq., can be reached at 571-272-0646. The central fax number for the USPTO is 571-273-8300.

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